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| 09/600,594 | 09/07/2000 | Milton F. Ferreira | 3673-3 | 5221 |

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EXAMINER

LUDLOW, JAN M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1743

DATE MAILED: 07/01/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/600,594

Applicant(s)

FERREIRA ET AL.

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37-40 is/are allowed.
- 6) ☒ Claim(s) 22-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 10, 2003 has been entered.
2. Claims 22-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the disclosure as originally filed for the negative limitation "by methods other than immunoassays" in claim 22. There is no support for "down to **at least** 0.3 ug/ml" in claims 22 and 32—"at least" is not supported.
3. The amendment filed February 10, 2003, entered June 10, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as described above with respect to claims 22 and 32.
4. Applicant is required to cancel the new matter in the reply to this Office Action.
5. Claims 25, 30, 32-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. Claim 25 recites "acetonitrile/2-propanol" as a non-polar solvent, but Lam teaches that acetonitrile is polar, and isopropanol, having an OH group, is polar as well. The scope of claim 32 is unclear in that the preamble refers to rifampicin, but the body of the claim refers to the broader term "the drug".

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

9. Determining the scope and contents of the prior art.
10. Ascertaining the differences between the prior art and the claims at issue.
11. Resolving the level of ordinary skill in the pertinent art.
12. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 22-, 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meucci et al.

15. Meucci teaches a method of testing for hydrophobic drugs in patient samples by precipitating with a mixture of zinc sulfate, alcohol (polar solvent) and acid, centrifuging and analyzing the supernatant (col. 2, col. 3, lines 25-52). The mixture can contain 100mM (0.1 M) zinc sulfate (col. 2, line 5) and 90-100% of the analyte is recovered (col. 3, line 21). The precipitating mixture is added in one step to the sample, the mixture vortexed and centrifuged (col. 7, lines 50-65). The reagent can be used to prepare other samples (col. 1, lines 50-65) for assays other than immunoassays (col. 2, lines 37-39).

16. Meucci fails to explicitly teach an example using assays other than immunoassay or the detection limit.

17. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the protein precipitation method of Meucci to prepare a sample and measure the analyte with a method other than immunoassay in order to use the sample preparation method with assays other than immunoassay as taught. With respect to the detection limit, in that the method of Meucci is substantially the same as that claimed, it is the examiner's position that the detection limit would be inherently met. Note that with the immunoassay, a detection limit of 15 ng/ml (0.015 ug/ml) is disclosed (col. 7, lines 19-20). With respect to claim 23, it would have been obvious to

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one of ordinary skill in the art at the time the invention was made to use a stronger concentration of zinc sulfate in a smaller added volume in order to provide the same concentration of zinc sulfate in the sample while minimizing sample dilution as was known in the art. With respect to claim 25, the non-polar solvent is recited in the alternative, and therefore the art need not teach the solvents to satisfy the claim. With respect to claim 27, acetic acid is a natural anti-oxidant (see, e.g., Vadhar, col. 15, line 53). It would have been obvious to use ascorbic acid for its known acidic function. With respect to claim 28, it would have been obvious to use other known assay methods after the sample preparation as taught by Meucci. With respect to claims 29-31, it would have been obvious to use the sample preparation method on other hydrophobic drugs as taught by Meucci.

18. Claims 32-36 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

19. Claims 37-40 are allowed.

20. The following is a statement of reasons for the indication of allowable subject matter: Claim 32 has been interpreted for purposes of examination as being limited to monitoring bioavailability of rifampicin. The prior art fails to teach or suggest the claimed method and kit for detecting rifampicin. Note that Meucci teaches propanol, but not acetonitrile/propanol or the other solvents. Note that Neither Bergqvist nor Lam teaches applicability to rifampicin.

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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22. Elsbach teaches that rifampicin is hydrophobic.
23. Bergqvist additionally teaches zinc sulfate precipitation with acetonitrile.
24. Applicant's arguments filed June 10, 2003 have been fully considered but they are not persuasive.
25. Applicant's arguments demonstrate a continuing lack of understanding of the scope of the instant claims. It is strongly suggested that applicant's registered representative review the legal meaning of the word "comprising" in contrast with the meaning of the phrase "consisting essentially of". In that the instant claims use the transitional word "comprising," the claims are considered "open" and any prior art reference which teaches or suggests the claimed steps PLUS any other additional steps or components, satisfies the instant claims. It is immaterial whether or not the exemplary method of Meucci requires additional steps or components because the instant claims do not preclude the additional steps or components. Further, Meucci teaches that the sample preparation can be used with other assay techniques, satisfying the unsupported (i.e., new matter) limitation "other than immunoassays".
26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers

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for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jan M. Ludlow
Primary Examiner
Art Unit 1743

jml
June 29, 2003